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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,265	12/03/2001	Masatsugu Maeda	06501-096001 / C2-105DP1P	5055
26161	7590	03/14/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			RIGGINS, PATRICK S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,265

Applicant(s)

MAEDA ET AL.

Examiner

Patrick S. Riggins

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 1/10/05 is acknowledged. Claims 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/10/05.

Specification

2. The disclosure is objected to because of the following informalities: sequence rules have not been fully complied with. See 37 C.F.R. 1.821-1.825. Specifically, the sequences present in Figures 1-7 and 13-14 should be referred to by SEQ ID NOs in the Brief Description of the Drawings. In the case where a SEQ ID NO already exists, as with figures 3-5 that SEQ ID number should be recited in all appropriate figures. In the case where no SEQ ID NO is present, as with figures 1 and 2, SEQ ID NOs should be assigned and referred to.

Appropriate correction is required.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. When assessing utility, one is to consider if the claimed invention possesses a specific and substantial utility and if so, if that utility is credible. Applicant has not disclosed any specific and substantial utility or a well-established utility for the claimed invention.

6. The claims are drawn to an isolated nucleic acid sequence comprising various isoforms of NR10, vectors that contain this nucleic acid, and transformants harboring the nucleic acid or the vectors. All utility assertions made with regard to NR10 function in the specification are general in nature and could not be considered specific and substantial. The specification on page 14 states: "The DNA may be useful for producing the above proteins [NR10] of the invention in vivo and in vitro. Furthermore, for example, it is possible to use the DNA for application to gene therapy and such of diseases arising from abnormalities of the gene encoding the protein of the present invention." Earlier, on page 8, the specification asserts that the proteins could be useful for the identification of an unknown hematopoietic factor, which aside from being unknown is not associated with any specific disease state. It is additionally asserted that the soluble forms of NR10 could be useful as an inhibitory factor for "treatment of diseases in which NR10 is implicated, such as leukemia." Firstly, there is no evidence supplied whatsoever suggesting that NR10 plays any role in leukemia and as such this statement is not in any way credible. Secondly, as there is no specified disease that NR10 or its putative unknown ligand have been identified to play a role in, and no evidence that any disease exists that a gene therapeutic approach would be useful for either the treatment or identification of these diseases, the asserted utility does not define a "real world" context of use. Any potential treatment of these putative unidentified

Art Unit: 1636

diseases would require further research to identify or reasonably confirm a “real world” context of use.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 1, 3, 5, and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1(c) is drawn to a nucleic acid that encodes a modified protein that is functionally equivalent the NR10 isoforms. As there is no data regarding a function for any of the NR10 isoforms, one would be unable to determine if the modified protein retained that function. Thus, it would not be clear to one of skill in the art that the inventors had possession of functionally equivalent, modified forms of any of the NR10 isoforms.

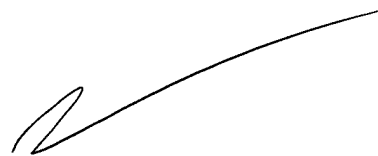
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER